K020703 P1/3

NOV 13 2002

510(K) SUMMARY

Scorpio® CR and PS Femoral Components and Scorpio®

Tibial Tray with Titanium Plasma Sprayed Coating

The Scorpio® CR and PS Femoral Components with Titanium Plasma Spray Coating, and the Scorpio® Tibial Tray with Titanium Plasma Spray Coating, are substantially equivalent to the predicate Cobalt Chromium alloy (CoCr) MicroStructured® Scorpio® CR (#K974556) and PS (#K962152) femoral components, and the MicroStructured® standard tibial trays of the Osteonics® Series 7000 Total Knee System (#K910990) in all material and design aspects. The following reflect the new characteristics of the subject components:

- The interior surfaces of the subject Scorpio® CR and PS femoral components with Titanium Plasma Spray Coating receive a titanium plasma spray coating instead of the MicroStructured® porous coating. All other design features of the femoral components are identical to the predicate devices.
- For the Scorpio®Tibial Tray with Titanium Plasma Spray Coating, the inferior surface of the tibial tray receives a titanium plasma spray coating (as opposed to a MicroStructured® porous coating), and the keel of the tray receives a thin titanium plasma spray coating. The plate of the subject tibial tray is 0.75mm thicker than that of the predicate tibial tray, and has been filled in with cobalt chromium alloy. Also, the screw hole configuration on the titanium plasma sprayed trays has been modified to allow greater angulation of the screws.

The plasma-sprayed commercially pure ("CP") Titanium coating is identical to the coating used on the predicate Howmedica Osteonics® femoral stems. The combination of a CoCr substrate and a plasma sprayed CP Titanium coating on a knee component is substantially equivalent to the CoCr substrate/Titanium alloy coating metal combination employed by the legally marketed predicate MCK® Total Knee System manufactured by Biomet, Inc.

Intended Use

The Scorpio® CR and PS Femoral Components with Titanium Plasma Spray Coating and the Scorpio® Tibial Tray with Titanium Plasma Spray Coating are intended for single-use, and are intended to be marketed for cemented fixation only. These femoral components and tibial tray are intended to be used with Osteonics tibial inserts and patellar components in total knee arthroplasty. These Scorpio® femoral components and the tibial tray are similar in design to the predicate Scorpio® CR and PS femoral components and Osteonics® Series 7000 tibial tray, with the exception the titanium plasma spray coating.

The following are the specific indications/contraindications for the Scorpio® CR and PS femoral components with Titanium Plasma Sprayed Coating, and the Scorpio® Tibial Tray with Titanium Plasma Sprayed Coating:

Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Contraindications:

The contraindications for the subject devices include:

- Any active or suspected latent infection in or about the knee joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity

- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Testing was provided to support the claim of substantial equivalence.

For further information contact:
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Regulatory Affairs Consultant
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401
(201) 934-4359 (Telephone)
(201) 760-8435 (Fax)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Stryker® Howmedica Osteonics
59 Route 17 South
Allendale, New Jersey 07401

Re: K020703
Trade/Device Name: Scorpio® CR and PS Femoral Components and Tibial Tray with Titanium Plasma Spray Coating
Regulation Number: 21 CFR §888.3560
Regulation Name: Knee joint, patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 22, 2002
Received: August 23, 2002

Dear Ms. Crowe;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

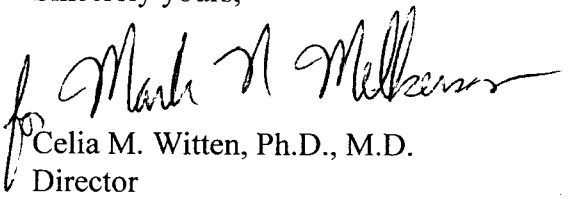
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K020703

Device Name: Scorpio® CR and PS Femoral Components and Scorpio® Tibial Tray with Titanium Plasma Spray Coating

Indications for Use:

The Scorpio® CR and PS Femoral Components with Titanium Plasma Spray Coating and the Scorpio® Tibial Tray with Titanium Plasma Spray Coating are intended for single-use, and are intended to be marketed for cemented fixation only. These femoral components and tibial tray are intended to be used with Osteonics tibial inserts and patellar components in total knee arthroplasty.

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The contraindications for the subject devices include:

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- Skeletal immaturity
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
K020703
(Prescription Use)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N. Melkerson 2002

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020703